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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,671	08/20/2003	Anthony J. Coyle	MPI00-212CP1CNIM	6437
30405	7590	06/21/2006	EXAMINER	
MILLENNIUM PHARMACEUTICALS, INC.			OUSPENSKI, ILIA I	
40 Landsdowne Street			ART UNIT	
CAMBRIDGE, MA 02139			PAPER NUMBER	

1644

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,671

Applicant(s)

COYLE ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/20/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment/remarks, filed 04/05/2006, are acknowledged.

Claims 1 – 23 have been cancelled.

Claims 24 – 33 have been added.

Claims 24 – 33 are pending.

2. Applicant's election of Group XI (original claims 20 and 21, drawn to a method for identifying a compound which binds to a human B7-H2 polypeptide) in the reply filed on 04/05/2006 is acknowledged. The newly added claims 24 – 49 read on the elected invention.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant further elected the Species of the “short form” of human B7-H2 (SEQ ID NO:4, or ATCC deposit No. PTA-2085).

Applicant's cancellation of claims drawn to non-elected species has rendered the species election moot.

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3. The newly added claims are directed to the following patentably distinct Species of the claimed Invention, wherein the binding of the test compound to the polypeptide is detected by:

- A. direct detection or a competition binding assay; or
- B. a two-hybrid or three-hybrid assay.

These species are distinct because the methods differ with respect to one or more of ingredients, method steps and/or endpoints. Furthermore, the examination of the different ingredients, method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

However, in the interest of compact prosecution, examination has been extended to include both species of the claimed invention.

Claims 24 – 33 are under consideration in the instant application.

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged.

However, the application USSN 09/620,461 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 24 – 33 of this application. Specifically, insufficient support was identified for the following limitations:

- A. nucleotide sequence [...] at least 83% identical to the nucleic acid sequence of SEQ ID NO:21 (claim 24);
- B. a membrane-bound form of an isolated polypeptide (claim 25); and

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C. a competition binding assay (claim 27).

Should Applicant disagree with the Examiner's factual determination above, it is incumbent upon Applicant to provide a showing that specifically supports the instant claim limitations.

5. It is noted that with regard to claims 24 – 33, added in an amendment filed 04/05/2006 (i.e. subsequent to the filing date of the instant application), no determination of priority date is being made at this time, in view of the New Matter rejection set forth below. For examination purposes, these claims are presently treated as if their priority date is the filing date of the instant application, i.e. 08/02/2003.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*. In addition, Applicant should avoid the use of the word "novel" in the title, as patents are presumed to be novel and unobvious.

7. Applicant's IDS, filed 08/20/2003, is acknowledged, and has been considered.

Applicant states that the references have been provided in the priority application USSN 09/620,461. However, certain references have not been located in the file of the priority application, and have been lined through. Applicant is invited to resubmit these references to complete the record. The Examiner apologizes for the inconvenience to Applicant.

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, e.g. on page 24, line 28. Applicant is

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required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. In addition, Applicant is requested to review the application for embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See MPEP § 608.01 and 608.01(p).

9. It is apparent that the plasmid deposited with ATCC as Accession Number PTA-2085 is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

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Given the disclosure and the claims encompassing the instantly claimed materials in U.S. Patent No. 6,635,950; the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to the plasmid deposited with ATCC as Accession Number PTA-2085 appear to have been satisfied.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 24 – 33 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification for support for the newly added claim limitations.

However, the specification does not appear to provide an adequate written description of the following limitations:

A. nucleotide sequence [...] at least 83% identical to the nucleic acid sequence of SEQ ID NO:21 (claim 24); and

B. a membrane-bound form of an isolated polypeptide (claim 25);

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The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

12. Claims 24 – 33 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The specification does not provide a sufficient enabling description of a method for identifying a compound which binds to:

A. a polypeptide comprising an amino acid sequence which is at least 85% identical to SEQ ID NO:4;

B. a polypeptide encoded by the nucleotide sequence which is at least 93% identical to SEQ ID NO:3; or

C. a polypeptide encoded by the nucleotide sequence which is at least 83% identical to SEQ ID NO:21.

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The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The claims recite a genus of polypeptides defined by percent identity to a reference sequence, but do not require that the encoded polypeptides share any testable functional activity, a feature deemed essential to the instant invention. Applicant has disclosed three forms of B7-H2 polypeptides, and thus has disclosed only three "variants". In the absence of a particular testable function and some structural basis for that function that must be maintained by the members of the genus, the claimed invention is not described in such a way as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1): 34 – 39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

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Further, even single amino acid differences can result in drastically altered functions between two costimulatory proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

In view of this unpredictability, the skilled artisan would not reasonably expect a generically recited polypeptide having, for example, at least 85% identity SEQ ID NO:4 to share the same function as the polypeptide of SEQ ID NO:4, and there is insufficient guidance to direct the skilled artisan as to such functional sequences. Thus the recitation of percent identity language does not allow the skilled artisan to make and use the encoding nucleic acids commensurate in scope with the instant claims without undue experimentation.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 24 – 33 are rejected under **35 U.S.C. 102(b)** as being anticipated by Coyle et al. (US Pat. Pub. No. 2002/0106730; 08/08/2002; see entire document).

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It is noted that although no determination of the priority date of the instant claims has been made at this time, for examination purposes these claims are presently treated as if their priority date is the filing date of the instant application, i.e. 08/02/2003 (see sections 5 and 11 above).

Coyle et al. teach and claim polypeptides identical in sequence to the instantly claimed polypeptides of SEQ ID NO:4, or encoded by a nucleic acid of SEQ ID NO:3, or deposited as ATCC No. 2085 (see entire document, in particular, e.g. claim 8). Coyle et al. further teach and claim methods for identifying a compound which binds to such polypeptides by contacting a polypeptide, or a cell expressing a polypeptide, with a test compound, and determining whether the polypeptide binds to the test compound (e.g. claim 20). Coyle et al. further teach that the sample may be an isolated polypeptide, or a cell comprising the polypeptide, wherein the cell may be a mammalian cell ; that the detection may be by a two-hybrid or three-hybrid assay; that the test compound may be labeled with a radioisotope or an enzymatic label; that the polypeptide may be a fusion protein; and that the binding may be detected by a cytokine production assay or a T cell proliferation assay (see entire document; in particular, e.g. the section "Screening Assays" at paragraphs 0185 – 0202).

Therefore, the reference teachings anticipate the instant claimed invention.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Venter et al., US Patent No. 6,812,339, earliest effective filing date 04/14/2000;
Mikesell et al., US Pat. Pub. No. 2002/0095024, earliest effective filing date 06/06/2000 (cited as reference A5 on IDS filed 08/02/2003);

Freeman et al., US Pat. Pub. No. 2002/0164600, earliest effective filing date 06/28/2000 (cited as reference A6 on IDS filed 08/02/2003).

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The references teach polypeptides which are 92.9% identical (Venter et al.) or 93.5% identical (Mikesell et al. and Freeman et al.) to the instantly claimed SEQ ID NO:4. The references also teach methods of identifying compounds which bind to such polypeptides (e.g. paragraphs 111 – 115 of Mikesell et al.)

Therefore, it appears that the teachings of the references anticipate the instant claimed invention (with the possible exception of claims 32 and 33). Alternatively, given the level of skill in the art at the time the invention was made, and the teachings of the references, it appears that the instantly claimed methods would have been obvious to one of ordinary skill in the art.

16. Conclusion: no claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

June 16, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D JD.
PRIMARY EXAMINER

TC 1600

6/16/06